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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,809	10/21/2003	Michael John Allen	P07,0140	9427

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1775	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,809	ALLEN ET AL.	
	Examiner	Art Unit	
	NATHAN BOWERS	1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-19 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13-19* is/are allowed.

6)☒ Claim(s) *21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thundat (US 6289717) in view of Thundat (US 6016686) and Oden (WO 0101121).

With respect to claims 21 and 26, Thundat '9717 discloses a method for using a motion sensor comprising at least one force transducing sensor (Figure 1:3) is provided in the form of a microcantilever that is positioned to interact dynamically with a specimen (Figure 1:13) in a fluid sample. Column 2, lines 22-36 and column 3, lines 31-49 indicate that a variety of biological specimens, such as cells, are capable of binding to a microcantilever. Changes in the subsequent deflection of the microcantilever can be detected in order to determine the presence and motion of the specimens. Column 5, lines 1-15 teach that this motion of the force transducing sensor can be measured by deflecting light from a laser (Figure 1:17) off of the microcantilever and onto a photodetector (Figure 1:19). Thundat '9717, however, does not expressly disclose a chamber capable of holding the motion sensor and the biological medium to be analyzed.

Thundat '6686 discloses a similar motion sensing method. Column 3, line 51 to column 4, line 29 indicates that a microcantilever (Figure 1:3) is capable of detecting

and measuring changes in the presence of certain physical and chemical parameters within the sample solution, such as hydrogen ion concentration. Since changes in the hydrogen ion concentration of biological samples is often linked to the activity of living organisms, deflections in the microcantilever can also be used to determine the presence of cells. This is taught in column 10, lines 10-17. A transparent chamber (Figure 10) for containing the motion sensor and biological fluids is disclosed.

Thundat '9717 and Thundat '6686 are analogous art because they are from the same field of endeavor regarding motion sensors comprising microcantilever devices.

At the time of the invention, it would have been obvious to practice the method disclosed by Thundat '9717 using a chamber capable of holding the biological medium and the force transducing sensor. The use of a chamber would have been advantageous because it would have allowed one the ability of conducting experiments in a clearly defined and contained structure that is protected against external contamination. Furthermore, a holding chamber for enclosing a sample would have been an essential and intrinsic component of any detection system involving the analysis of liquids. The use of chambers in biological analytical procedures to contain fluids and instruments is well known in the art.

The Thundat references still differ from Applicant's claimed invention because neither reference expressly discloses that motile frequency, and/or binding behavior of a biological specimen on the cantilever is measured to facilitate measuring concentration of an analyte. Although Thundat '6686 depicts in Figure 12 that cantilever bending over

time in response to fluid analytes is measured, Thundat '6686 does not expressly teach that the sensor is responsive to individual analyte contact and collisions.

Oden discloses a microcantilever (Figure 1:3) that is coated and otherwise configured to interact with analytes in a sample solution. Oden teaches on page 4, lines 22-34 that oscillation frequency of the microcantilever is measured before, during and after a binding event to determine a change in frequency attributable to the presence of the analyte. Claim 1 further recites that concentration of an analyte in the solution is determine by comparing observed frequency shifts. Motile frequency of analytes can be inferred from this detectable change in cantilever movement.

The Thundat references and Oden are analogous art because they are from the same field of endeavor regarding microcantilever sensing systems.

At the time of the invention, it would have been obvious to use the Thundat '9717 system to measure the motile frequency of a plurality of successive biological analytes in order to determine analyte concentration. As evidenced by Oden, it is well known in the art to determine analyte concentration based on the frequency at which the cantilever is deflected. One of ordinary skill would have understood that observed variations at which the cantilever vibrates are inherently tied to the rate at which motile analytes impact the cantilever.

With respect to claims 22-25, Thundat '9717 and '6686 and Oden disclose the method set forth in the 35 U.S.C. 103 rejections above. Although not expressly stated, the device proposed by Thundat '9717 is inherently capable of detecting motile cells,

such as sperm, since microcantilever detection devices are provided with coatings that encourage the adherence of desired biological analytes. It is well within the purview of one of ordinary skill to use the Thundat '9717 method to evaluate a plurality of well known and medically important cells and biochemicals.

2) Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Welland (US 20030222232) in view of Oden (WO 0101121).

With respect to claims 13 and 21, Welland discloses a motion sensing method comprising a chamber (Figure 1:4) for holding a medium, wherein the medium includes a sample. Paragraphs [0001] and [0002] indicate that the motion sensor is designed to determine the presence of pharmaceutical analytes in a biological sample fluid. According to paragraphs [0005]-[0009], the chamber includes at least one force transducing sensor (Figure 1:3) in the form of a microcantilever positioned to interact dynamically with the sample. Paragraph [0031] teaches that a photodiode (Figure 1:2) is provided for detecting light reflected off of the microcantilever from a laser diode (Figure 1:1). Welland teaches that the light is passed through a transparent substrate before it enters the chamber and contacts the cantilever. This allows one to determine when and to what degree the force transducing sensor interacts with analytes in the biological sample.

Welland still differs from Applicant's claimed invention because Welland does not expressly teach that motile frequency, and/or binding behavior of a biological specimen on the cantilever is measured to facilitate measuring concentration of an analyte.

Oden discloses a microcantilever (Figure 1:3) that is coated and otherwise configured to interact with analytes in a sample solution. Oden teaches on page 4, lines 22-34 that oscillation frequency of the microcantilever is measured before, during and after a binding event to determine a change in frequency attributable to the presence of the analyte. Claim 1 further recites that concentration of an analyte in the solution is determine by comparing observed frequency shifts. Motile frequency of analytes can be inferred from this detectable change in cantilever movement.

Welland and Oden are analogous art because they are from the same field of endeavor regarding microcantilever sensing systems.

At the time of the invention, it would have been obvious to use the Welland system to measure the motile frequency of a plurality of successive biological analytes in order to determine analyte concentration. As evidenced by Oden, it is well known in the art to determine analyte concentration based on the frequency at which the cantilever is deflected. One of ordinary skill would have understood that observed variations at which the cantilever vibrates are inherently tied to the rate at which motile analytes impact the cantilever.

With respect to claims 22-25, Welland and Oden disclose the method set forth in the 35 U.S.C. 103 rejections above. Although not expressly stated, Welland's device is inherently capable of detecting motile cells, such as sperm, since microcantilever detection devices are provided with coatings that encourage the adherence of desired biological analytes. It is well within the purview of one of ordinary skill to use the

Welland method to evaluate a plurality of well known and medically important cells and biochemicals.

Allowable Subject Matter

Claims 13-19 are allowed.

The prior art does not disclose, in the claimed environment, a method for determining residence times of motile specimens on a force transducing sensor, wherein an interaction of the motile specimens with the force transducing sensor is categorized as one of an impact, an oscillation, and a retention to facilitate indentifying a binding behavior of the motile specimens. The Thundat, Welland and Oden references (as described in the rejections above) represent the closest prior art by describing the detection of analytes using at least one microcantilever. Oden, in particular, teaches that the concentration of analytes may be determined by evaluating a change in the vibrational frequency of the cantilever. None of these references calculating the residence time of the motile specimen on the sensor, or categorizing the binding behavior of the motile specimen to the sensor.

Response to Arguments

Applicant's arguments filed 07 April 2011 with respect to the 35 U.S.C. 103 rejections involving claims 21-26 have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, new grounds of rejection have been made in view of the Oden reference, which more

clearly describes detecting analyte concentration by evaluating observed changes in vibration frequency.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Nathan A Bowers/
Primary Examiner, Art Unit 1775